U.S. Department of Justice

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June 22, 2021

BY ECF
The Honorable Mary Kay Vyskocil
United States District Judge
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, New York 10007

Re: *Pfizer Inc. v. United States Department of Health and Human Services, et al.*, No. 20 Civ. 4920 (MKV)

Dear Judge Vyskocil:

This Office represents the defendants (the "Government") in the above-referenced action. We write respectfully in response to Pfizer's second supplemental letter brief, filed late last night, discussing an opinion issued by a Delaware district court on June 16, 2021. *See* ECF No. 75 ("Pfizer Ltr."); *see also AstraZeneca Pharms. LP v. Becerra*, C.A. No. 21-27-LPS, 2021 WL 2458063 (D. Del. June 16, 2021) ("*AstraZeneca*"). In sum, Pfizer's letter is wholly irrelevant to the issues in this case. To the extent the Court is inclined to consider them, the letter and the *AstraZeneca* opinion in fact highlight the infirmities of Pfizer's claims and arguments in this matter.

First, Pfizer's letter and the *AstraZeneca* opinion are legally, factually, and procedurally irrelevant to this case for several reasons:

- The December 2020 Advisory Opinion issued by the U.S. Department of Health and Human Services Office of General Counsel, which is the subject of *AstraZeneca* (the "AstraZeneca AO"), offered HHS-OGC's guidance and views regarding a particular Public Health Service Act program and the obligations of drug manufacturers thereunder, *see AstraZeneca*, 2021 WL 2458063, at *3—an issue that has nothing to do whatsoever with the AKS or the subjects of this case, namely HHS-OIG's actions in response to Pfizer's request for AOs regarding its two proposed tafamidis subsidy programs.

- Pfizer's primary point in its letter is that both the AstraZeneca AO and the HHS-OIG AO regarding Pfizer's proposed Direct Subsidy Program (the "Pfizer AO") are reviewable agency actions under the APA. Pfizer Ltr. at 1. But the Government has never contested the reviewability of the Pfizer AO under the APA. *E.g.*, ECF No. 57 at 8 n.5. The Government has noted that the Court lacks

jurisdiction over Pfizer's request for a free-standing declaration opining on the application of the AKS to the proposed *Indirect* Subsidy Program, because the request is untethered to a valid cause of action, *see id.* at 8, ECF No. 45 at 22[1]; and argued also that if the Court were to identify any violations of the APA here, remand would be the more usual and appropriate remedy, *e.g.*, ECF No. 45 at 25.

- According to Pfizer, *AstraZeneca* compels the conclusion that the Court should not, in this case, accord any deference to the views of HHS-OIG in the area of AKS interpretation and enforcement. Pfizer Ltr. at 1. *AstraZeneca* stands for no such proposition. In *AstraZeneca*, the court disagreed with HHS-OGC's characterization of its AO as consistent with past Government guidance, opining that the AstraZeneca AO represented a "material shift" in the Government's position on the relevant federal program. *E.g.*, *AstraZeneca* at *6.[2] In this case, Pfizer has never argued that the Court should be skeptical of the Pfizer AO on the ground that it supposedly departs from prior agency guidance. To the contrary, Pfizer's central premise in this case is that decades of HHS-OIG interpretation and enforcement activity, up to and including the Pfizer AO, evince a consistent and, according to Pfizer, overly restrictive view of the AKS. *See, e.g.*, ECF 34 at 2, 20. Pfizer simply does not like HHS-OIG's long-standing interpretation, and would like the Court to use this case as a vehicle to rewrite and revise it in a declaratory judgment.

Pfizer's reliance on *AstraZeneca* inadvertently highlights infirmities in several of Pfizer's claims and arguments in this case. For example, Pfizer argues that the Court should view the Pfizer AO as "the agency's definitive position," a description that the *AstraZeneca* court applied to the AstraZeneca AO. *See* Pfizer Ltr. at 1; *AstraZeneca* at *7. Indeed, HHS-OIG set forth a clear position in the Pfizer AO: While certain aspects of the Direct Subsidy Program as described by Pfizer appeared to pose substantial risks under the AKS, HHS-OIG could not and would not reach a "definitive conclusion regarding the existence of an [AKS] violation," since any such conclusion would require "consideration of all of the facts and circumstances of the arrangement *as implemented*." *See* ECF No. 45 at 8 (emphasis added). In light of HHS-OIG's clearly expressed sensitivity to the facts and circumstances of the proposed program *once it is actually implemented*, the Court should reject Pfizer's invitation to simply assume that an enforcement action is so inevitable and imminent here that the Court must preemptively

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[1] Pfizer continues to insist that it has pled a "separate cause of action under the Declaratory Judgment Act." Pfizer Ltr. at 1. Pfizer has never addressed the hornbook principle that the Declaratory Judgment Act "is procedural only, and does not create an independent cause of action." *Carr v. DeVos*, 369 F. Supp. 3d 554, 563 (S.D.N.Y. 2019) (quoting *Chevron Corp. v. Naranjo*, 667 F.3d 232, 244 (2d Cir. 2012)).

[2] Although the court in *AstraZeneca* opined that the AstraZeneca AO reflected an "unjustified assumption" that the interpretation set forth in the AO was "compelled by Congress," *AstraZeneca* at *11, the court also noted its view that HHS-OGC's interpretation in the AstraZeneca AO "is permissible." *Id.*

pen its own advisory opinion (in the form of a declaratory judgment) about the scope of the AKS and its application to Pfizer's proposed programs.

Moreover, the *AstraZeneca* court did not leap straight to the issuance of declaratory judgments in that case, as Pfizer asks the Court to do here. *AstraZeneca* at *11. Rather, the *AstraZeneca* court asked for additional briefing on the most appropriate remedy, "be it setting aside the [AstraZeneca AO], vacating it with respect to AstraZeneca, remanding to HHS, and/or something else." *Id.* Similarly, here, even to the extent that any of Pfizer's claims are well-pleaded, for the reasons laid out in the Government's briefing, the appropriate remedy would not be the wholesale provision of preemptive advisory opinions regarding proposed programs that have never been implemented.

We thank the Court for its attention to this matter.

Respectfully submitted,

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cc (via ECF): All Counsel of Record